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(54) PERMANENTLY IMPLANTABLE FIXTURE MEANS FOR PROTHESES AND THE LIKE

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Permanently implantable fixture means for protheses and the like.

At implantation of various fixture means for protheses of natural or artificial material in a human body or in any other biologically living material, said fixture means usually have to be fixed either permanently or at least for a given period of time, during which said fixture means may attach on its new place in the organism. These protheses may be of many different kinds, for instance leg protheses, articulation protheses and so on, but as a typical example implantation of a fixture means for permanent application of teeth protheses will be mentioned. The present invention refers to such an implantable device which is in itself permanently implantable in bone or other skeletal tissue existing in the organism.

Various permanently implantable fixture means of this type are already known, but they have in many a case proved unsatisfactory, as they are subjected to different repellation processes, whereby the implantated device, (below as a matter of simplicity called "protheses", even if they should not form such protheses in a sense) have lost in reliability and in bond with the organism. In other cases, the purely mechanical structure and construction of the devices have been of such a kind, that they could not reliably remain in bond with the organism, and they have shown a tendency to get loose.

When fixture means for protheses are implanted, this usually takes

place in skeletal tissue in the body. Therefore, one cannot avoid that a damaging incision has to take place in the skeletal tissue as well as in the weak epitholial tissue situated outside of same. If a tooth protheses has thus to be attached by means of such a device, one has to uncover the jaw-bone whereby it is necessary to cut through connective tissue as well as the gums. It has proved that the wounds thereby emanating in the skeletal and week tissue are very difficultly healed, if the protheses is, attached to the fixture means during the healing period and it is also very difficult to provide a good connection between the fixutre means and the skeletal tissue, if the protheses is attached to the fixture means during the healing period. Therefore, it has been proposed to separate the fixture means from the protheses, and first to apply the fixture means suitable for the purpose in the bone or the skeletal tissue, suitable for the purpose, and thereafter to leave these parts to be healed together, and only after completed or approximately completed healing together between the fixture means and the skeletal tissue, and after healing of the damage caused by the application of the fixture means (to apply) the protheses is applied to the fixture means.

In order that this shall be possible, the fixture means must however extend out from the skeleton tissue as well as from the weak tissue by such a distance, that there is a possibility of attachment. It now proves, that the healing is made essentially more difficult and thereby also less good by this, because the extending part of the fixture means will, during the healing period when the fixture means does not carry up the protheses, be subjected to mechanical strains by which the healing parts may be moved. A contamination of the healing wound may also take place from the outer surrounding through the passage formed by the perforated part of the fixture means. Therefore, healing will take place during essentially more favourable circumstances if the fixture means is completely embeded in weak tissue

and/or skeleton tissue during the healing period. However, as mentioned above, difficulties will then arise at the application of the protheses on the fixture means.

The present invention thus relates to a permanently implantable fixture means for protheses or the like, composed by at least two parts, and intended for fixture of protheses to skeletal tissue.

According to the invention a first part, the fixture unit, is intended to be applied in such a way in the skeletal tissue, that it will remain embedded in tissue during all of the time for healing the damage, created at the preparation of the place for the fixture unit and during healing said fixture unit, and a second part, the distance unit, which is of such a character that it may be attached to the fixture unit so that it will pass through the weak tissue which covers the skeletal tissue. The distance unit is intended to combine the fixture unit, embedded in skeleton tissue, with a protheses applied outside of the weak tissue.

Further details of the invention will be evident from the following description of a number of forms of execution of the invention, but it is understood that the invention shall not be limited to these forms of execution, but that all different kinds of modifications may occur within the scope of the invention.

In the drawings, Figure 1 shows the part of the fixture means to be embedded in skeleton tissue, below referred to as the fixture unit,whereas Figure 2 shows the distance unit pertaining thereto, that is the unit which is situated above the skeletal and weak tissue at least to an essential part, and to which the protheses is intended to be attached. As these two units comprise a plurality of details, and are releasably combined to each other, the units have in both figures been shown in so-called exploded projection. Figure 3 shows the fixture unit according to Figure 1 during healing, and Figure 4 shows the fixture unit according to Figure 1 after completed healing with the distance

unit according to Figure 2 applied in connection with the fixture unit. Figure 5 shows a different form of execution of the fixture unit, and Figure 6 shows the distance unit pertaining thereto.

In the arrangement according to Figure 1, the fixture unit comprises a bolt 10, which is threaded on its outer side. These threads are intended to be placed into a bored and threaded hole in the jaw-bone at permanent implantation of a fixture means for a tooth prosthesis. The bolt is bored from below to form a well 11, and holes 12 run from the sides through the threads into well 11. The bolt section further narrows downwardly at 13. Also at the upper end a well 14 is provided, which is threaded on its inner side for a purpose, which will be evident from the following. For screwing the bolt into the jaw-bone a screw driver groove 15 is arranged in the edge of the well 14. A bridge 16 is provided between the two wells 11 and 14.

The intention is that this bolt should serve as a fixture unit in order later on to be combined with a distance unit shown in Figure 2. This, however, should not take place until there has been a healing between the bolt and the skeletal tissue in the jaw-bone, and further a given attachment healing has taken place. The holes 12 are provided for promotion of said attachment healing. Newly formed skeletal tissue then will get an opportunity to grow into the holes 12, whereby screwing out or threading out of the bolt is effectively prevented. The sides of the bolt as well as the cuts of the threads should further be treated in such a way, that they will get a rough and/or porous surface, for instance by etching, blasting, latticing or the like. Thus attachment healing between the skeleton tissue and the bolt is further promoted.

It may be assumed that if separated skeleton tissue material exists in the interior of the cavity 11, this may also promote an improved attachment healing through the holes 12. Such material will be scratched away from the skeleton tissue during the screwing in of the bolt 10 due to

co-operation between the sharp edges of the holes 12 and the fact that the bolt narrows downwardly as indicated at 13. Each of these circumstances already per se causes a given scraping off, and the scraped material will be driven through the holes 12 into the well 11.

The fixture unit preferably is provided with a tightening device, which is active during the healing period. As such a tightening device a ring 17 functions, which is applied on the upper part 18 of the bolt, which is for this purpose made slightly conical. The ring is provided at its lower end with a sharp edge 19, which has for its purpose when applying the ring 17 to enter into the bottom of a small extension about the hole, which has been bored in the jaw-bone to make room for the bolt 10. Thereby a tightening is created, by which one may effectively prevent impurities or non-desired weak tissue to enter into the hole in the jaw-bone and thereby prevent good healing. The ring 17 may remain pressed into its place all of the healing period by means of a screw 20, meshing into the internal threads in the well 14. The head of said screw tightingly contacts an inclined flange 21 on the ring.

In the foregoing the procedure when inserting the fixture unit has been described as if the bolt 10 should first be screwed into the hole in the jaw-bone, and thereafter the ring 17 should be applied, and finally the ring 17 should be attached to the bolt 10 by means of the screw 20. Of course, the procedure may be thus performed, but in practice it is nevertheless in many a case more suitable in advance to combine the bolt 10, the ring 17 and the screw 20 into one single unit, compriaing all of these three parts, and to introduce this unit in the hole in the jaw-bone. The unit is shown in this state in fig 3.

In this state as shown in fig 3, it should remain during all of the healing period, which may take a time from some weeks until some months, depending upon the circumstances in the specific case. The weak tissue,

initially covering the actual region of the jaw-bone, and which has been folded away during preparation of the hole in the jaw-bone, is replaced by means of sutures or in other suitable way above the fixture unit, so that the unit will be completely covered. Thereby, it will be well protected during all of the healing porcedure against mechanical influence as well as chemical and bacteriological influence, and the healing will take place without disturbance.

After completed healing, the weak tissue above the ring 17 and the screw 20 is cut away, so that these parts are uncovered. Thereafter the ring 17 and the screw 20 are removed. After this one has to mount the distance unit shown in fig 2. In the illustrated embodiment it comprises a sleeve 22, which is also provided with a sharp edge 23 for the same purpose as the edge 19 on the ring 17 just mentioned. The outer side of the sleeve 22 is also formed at its lower end as exactly as possible equal to the outer side of the lower part of the ring 17, so that the lower part of the sleeve will be completely adapted to the tissue channel, exposed by the ring when it is removed. The sleeve 22 finally is attached by means of a screw 24, which is provided with a threaded male part for mashing into the internal threads in the well 14 in the fixture unit, and with a femal part for co-operation with screws, by means of which the protheses is attached. The attachment should be of such a kind that no turning movement of the distance unit will later on occur relative to the bolt of the fixture unit. The complete arrangement then will look as indicated in fig 4. A screw driver grove 25 is arranged for screwing in the screw 24.

It was mentioned above that the bolt 10 should suitably be provided in one way or another with a rough and/or porous surface, because the healing together between the tissue and the bolt would thereby be promoted. Certain other parts, however, should as far as possible be prevented from healing together with the tissue. This is especially the case with the ring

17, which should only be used temporarily during the healing period. It also concerns all parts of the sleeve 22 except the lowermost part, at which a given tissue attachment during the healing may be desired. The parts, which are not desired to be attached to the tissue during the healing period, should be smooth.

The choice of the material in different parts is of exceedingly great importance. There are a lot of different materials from which a fixture means according to the present invention could be produced but there are still more materials which are completely unsuitable for the purpose. The suitable materials are called tissue friendly, because neither the skeletal tissue nor the weak tissue shows any tendency of repelling them. The material should be chemically as well as biologically compatible with the tissue. However, one has also to look for a lot of other demands on the material for the fixture unit being satisfied, amongst which the following ones should be mentioned.

For natural reasons the fixture unit will have very small dimensions. Nevertheless, the fixture unit must be capable of retaining the prosthesis when it is subjected to rather big strains. This means that the fixture unit should have a very high rigidity. It must further have, practically speaking unlimited aging permanence. The fixture unit must in spite of being so small be possible to be worked with a high degree of accuracy, which causes that one must require a high degree of workability of the material in the fixture unit. Finally, the material must be chemically inert against all such constituents, which may exist in foodstuffs as well as in the normal materials existing in the mouth cavity, and against all kinds of bacteriological attacks.

Some metallic alloys are known, closely related to stainless steel, which satisfy these demands, and further there are some tissue friendly plastics which satisfy them. The best material hitherto known, however, certainly is pure or weakly alloyed titanium. It is well known within surgery that titanium has favourable properties in the above mentioned respects.

The above will apply in first place regarding the choice of material for the bolt 10, which should be permanently attached to the jaw-bone. The ring 17, however, may be made from some other material, and if this material

possesses a given elasticity or plasticity, so that it will easily adapt itself to the jaw-bone, this is only to be regarded as an advantage, because thereby the tightening will in some cases be improved.

Instead of titanium one may use some other material for the parts, which were above provided to be made from titanium, said metal being coated by titanium, for instance by a galvanic process.

It is not necessary that the bored hole in the jaw-bone be threaded on its inner side, or that the inwardly directed part of the bolt 10 on the fixture unit be provided with outward threading, even if one can obtain in this way an extremely good bond between the jaw-bone and the fixture unit. As a matter of fact one may also obtain a good bond with the bored hole in the jaw-bone without said hole being threaded, for instance if the bolt part is dimensioned so wide, that it squeezes in the hole, however not so much, of course, that it will burst the bone material or cause fissures in said material when pressed down therein. The sides of the bolt may therefore be smooth but not slippery, and they may be provided with barb-like grooves or projections which permit the driving in of the bolt but prevent its drawing out from the hole bored in the jaw-bone.

Another way for attachment of the bolt is shown in Figures 5 and 6. As in the earlier described embodiment the bolt 10 is provided with a number of holes, for instance four such holes, leading into the cavity 11. The edge below these holes 12, however, is cut up in this case by means of slots, so that as many tongues are formed as the number of holes 12. The inner sides of the tongue points 27 thereby are conically faced inwardly and downwardly. A disk 28 is introduced into the face edge formed in this way, said disk being so dimensioned that it rather exactly adapts to the inner diameter of the well 11. Now, one introduces a screw 29 with a pinformed end 30 into the internal threads in the bolt 10, which is provided in this case with a threaded hole running quite through; until the point 30 exactly gets into contact with the disk 28, and thereafter the bolt 10 is introduced into the hole bored in the jaw-bone. Thereafter one screws the screw 29, so that its point will press the disk 28 between the inwardly inclined flanges 27 on the tongue points,

and these are forced to expand outwardly. A very strong and good bond is obtained in this way.

The specific advantage with this arrangement is that one does not need to make the elaborate boring of two wells 11 and 14, see Figure 1, but one can use one single bore running quite through. The intermediate wall 16 in this case will be replaced by the screw 29.

Also in another respect the arrangement according to Figures 5 and 6 differs from the above described arrangement. In the arrangement according to Figures 1 and 2, tightening against impurities entering from outside is substantially obtained by a sharp edge 19 on the ring 17 during the healing period and thereafter during the permanent period by a corresponding sharp edge 23 on the sleeve 22 of the distance unit. In the arrangement according to Figure 6 one has instead provided the bolt with a flange 35 all around, and this flange carries on its lower side up such a sharp edge 31 as mentioned above. Above the flange 35 there is in this case a small recess 32, intended for the lower side of the sleeve 22 of the distance unit. The part 24 of the distance unit is made in the same way, as according to Figure 2.

When the fixture unit is mounted, it must be completely pure and sterile. Usual sterilization methods have in some cases not proved sufficient for this purpose. Preferably one should use especially highly effective cleaning and sterilization methods amongst which may be mentioned subjecting the units to ultra sonic waves of high power, in combination with the application of chemically active cleaning and sterilizing mediums.

It is important, that the distance means should not leave any slot between its lower edge and the part of the bolt in contact therewith. In the arrangement according to Figures 1 and 2 this has been avoided by the sleeve 22 of the distance means being placed with an inwardly conical part over the outwardly conical part of the upper end of the bolt 10. In the arrangement according to Figures 5 and 6 the lower edge of the sleeve 22 is exactly adapted to the form of the recess 32 in the upper part of the bolt 10. In both cases one gets good tightening.

This tightening, however, could be destroyed if the distance means

is subjected to any disturbing mechanical influence in sideward direction, for instance through a blow in the jaw. It is then important to damp such strains by interconnection of some material elastically resilient to a suitable degree between the prosthesis and the bolt. For that reason the screw 24 of the distance unit is made of some suitable elastic material, e.g. plastic. It is further provided with an especially small neck 33 for increasing the elastic resiliency. At very strong strains in sideward direction against the prosthesis the neck 33 may even be broken off, so that the connection between the bolt 10 and the distance unit will cease. It is then usually an easy matter to remove the prosthesis and to put a new distance means in without damage to the emplant.

In order that the distance unit should have the required freedom of movement without its sleeve 22 following any such movement and transferring such movement to the fixture unit, a slot 34 is provided all around between the sleeve 22 and the screw 24.

The sleeve 22 should be made from metal, for the above mentioned reasons preferably of titanium. This should be polished so that it is bright in its upper part for preventing impurities from attaching to its surface. However, it is desirable that the surface of the part close to the fixture unit is of the same character as the surface of the fixture unit for making it easier for the tissue to heal in attachment thereto.

There are tissues sensitive to heat and cold in the jaw-bone. Therefore it is also important, that the prosthesis be heat insulated from the jaw-bone. If the parts of the fixture unit are made throughout from metal, a heat conduction bridge will be created, which could cause shocks of temperature in the tissue for instance at consumption of hot or a cold drink. Therefore, one should interconnect in a suitable place in the way of this heat conduction a material of low heat conduction power for causing an interruption of the heat conduction bridge. It is especially suitable thereby to make the bolt 24 in the distance unit of some heat insulating plastic. Most plastics having the desired elasticity for damping the mechanical shocks are also well suited for damping heat shocks of the said kind.

However, it is desirable that the surface of the part close to the fixture unit is of the same character as the surface of the fixture unit for making it easier for the tissue to heal in attachment thereto.

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THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A device for mounting a prosthetic on skeletal tissue comprising a fixture unit for inserting in a cavity provided in skeletal tissue such that said fixture unit is completely embedded therein, said fixture unit including an innermost part to be inserted into the innermost portion of said cavity and a temporary outermost part of compact dimensions mating with and releasably secured to said innermost part, and a distance element mating with and securable to said innermost part of said fixture unit in the same way as and after removal of said temporary outermost part, said distance element proturding from said fixture unit outwardly for connection to said prosthetic, said distance element including means for securing a prosthetic thereto.

2. A mounting device according to claim 1 wherein the surface of the innermost part of said fixture unit includes means for promoting adhesion thereof to skeletal tissue.

3. A mounting device according to claim 2 wherein the outer surface of the outermost part of said fixture unit is smooth to minimize adhesion thereof to skeletal tissue.

4. A mounting device according to claim 1 wherein the innermost part of said fixture unit includes at least one aperture to permit ingrowth of skeletal tissue.

5. A mounting device according to claim 1 wherein said innermost part of said fixture unit is provided with a flange adapted to abut said releasable outermost part, said distance element abutting said flange when secured thereto.

6. A mounting device according to claim 1 wherein said innermost part of said fixture unit includes a threaded hollow core, said core tapering inwardly at the inner end thereof, and wherein said outermost part is secured thereto by means of a bolt passing into said threaded core, said bolt also co-operating with said inner end to provide an expansion bolt for tightening said fixture unit in a skeletal cavity.

7. A mounting device according to claim 1 wherein said innermost part of said fixture unit includes a threaded hole for securing said distance element and said outermost part, respectively, thereto.

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8. A mounting device according to claim 1 wherein the surface of said innermost part is provided with threads for screwing into a cavity provided in skeletal tissue.

9. A mounting device according to claim 8 further including holes in the outer surface of said fixture unit to permit ingrowth of skeletal tissue the edges of said holes being sufficiently sharp to cut away portions of skeletal tissue as the device is being screwed into said cavity.

10. A mounting device according to claim 7 wherein said threaded hole terminates in the body of said innermost part of said fixture unit.

11. A mounting device according to claim 1 wherein said distance element comprises a first sleeve part and a second bolt part located within said sleeve part and adapted to secure same to the innermost part of said fixture unit.

12. A mounting device according to claim 11 wherein said bolt part is fabricated of a resilient material.

13. A mounting device according to claim 12 wherein the inside diameter of said sleeve is larger than the outside diameter of said bolt to accommodate changes in the relative positions of said bolt and sleeve members.

14. A mounting device according to claim 11 wherein said bolt part is provided with an area weakened sufficiently to preferentially break in the event that a predetermined force is applied to said distance element.

15. A mounting device according to claim 1 wherein a portion of said distance element located between said prosthetic and said fixture unit is heat insulating.

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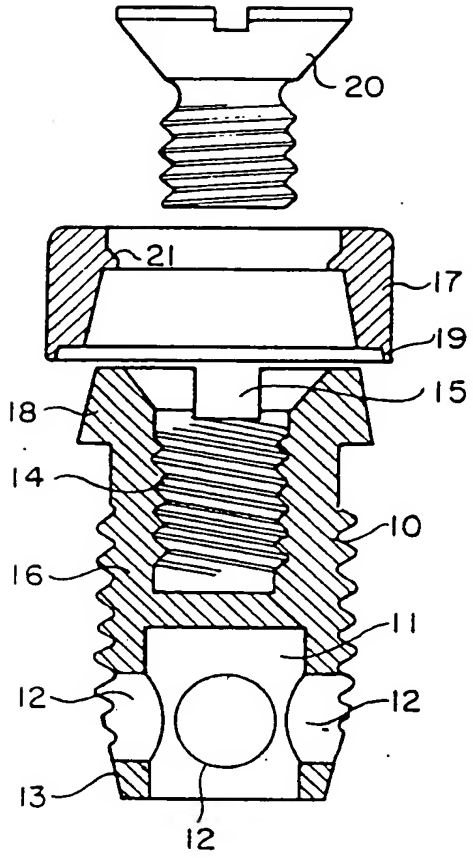


Fig.1

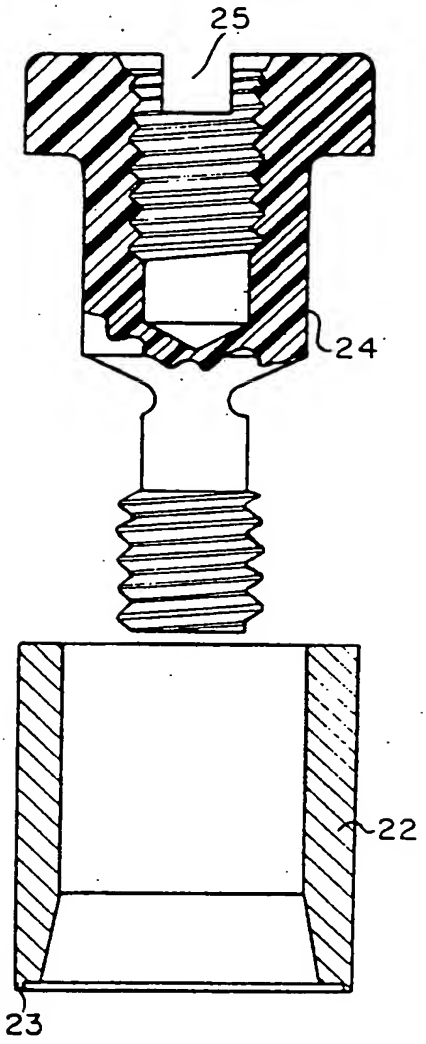


Fig.2

Fig. 4

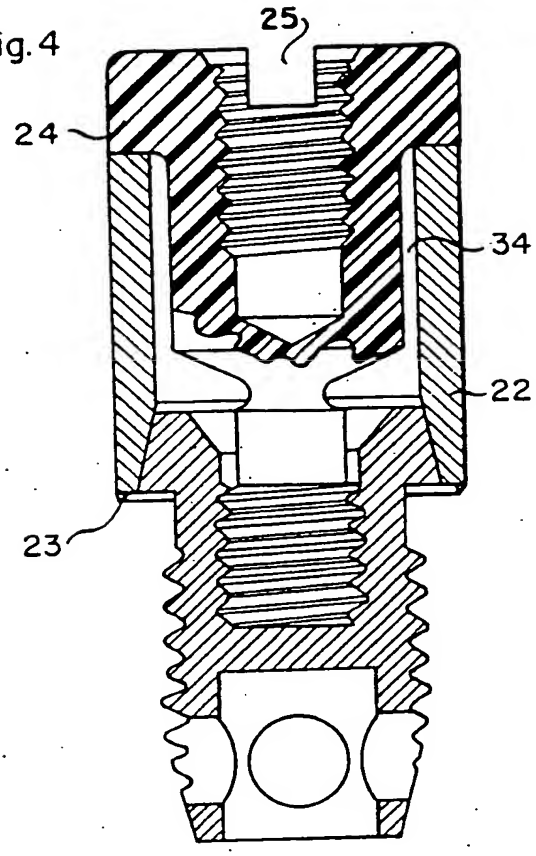


Fig. 3.

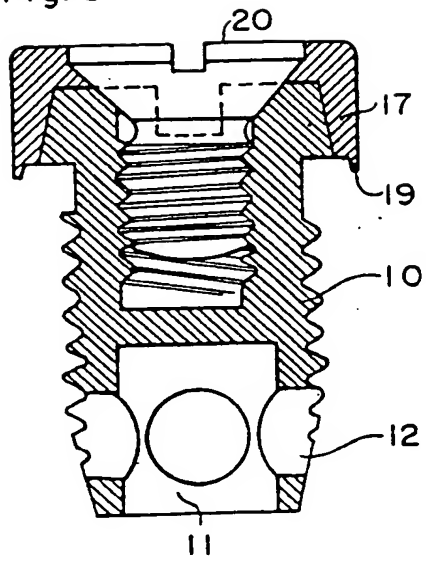


Fig. 6

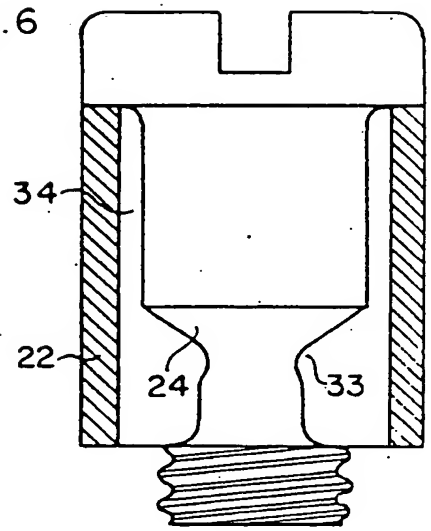
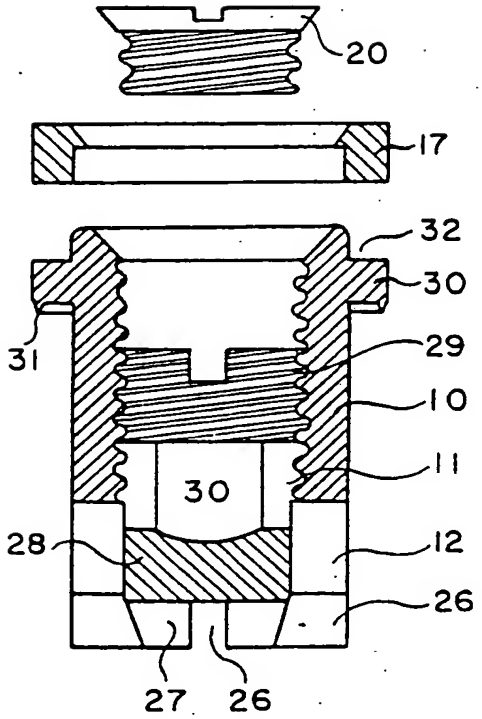


Fig. 5



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